MAY 10 2011

510(k) SUMMARY
K110121

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Part 807.92.

Submitter's Name: Microsurgical Laboratories, dba Wexler Surgical Supplies
11333 Chimney Rock Road, Suite 110
Houston, TX 77035
Telephone: (713) 723-6900
Fax: (713) 723-6906
Contact person: Mr. Danny Fishman, COO

Date of Summary: March 29, 2011

Device Names:
Trade Name, Common Name: Endoscope accessories, various
Classification Name: Endoscope accessories (21 CFR, Part 876.1500, GCJ)

Legally Marketed Device to which Equivalence is Claimed: The legally marketed predicate devices are the Scanlan® thoracoscopic scissors, clamp, forceps, and needle holder (K945474) manufactured by Scanlan International, Inc., determined to be substantially equivalent to a legally marketed (preAmendment) device on December 5, 1994.

Device Description: The Wexler Endoscope Accessories is a group of instruments used during endoscopic procedures such as thoracoscopy and laparoscopy. The instruments include clamps, forceps, needle holders, and scissors. The devices are made of stainless steel, and are supplied non-sterile.

Intended Use: The Wexler Endoscope Accessories are indicated for use in endoscopic surgical procedures to provide minimally invasive handling during the instrument's intended function. Clamps and forceps are used to grasp tissue or other items in the surgical field, while scissors are used to cut tissue or other items and needle holders are employed during the suturing process.

Descriptive Summary of Technological Characteristics and Those of Predicate Device: The indications for use, principles of operation, and device design of the Wexler Endoscope Accessories are virtually identical to those of the predicate devices, the Scanlan thoracoscopic instruments. Both series of devices are made of stainless steel, and share technological characteristics common to all instruments of their types. There are no significant differences in either technology or performance specifications. The Wexler Endoscope Accessories devices are supplied non-sterile, and the devices are subjected by the user to the sterilization cycle specified by the institution.

Conclusion: The information and data provided in this 510(k) Notification establish that the Wexler Endoscope Accessories is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 1 0 2011

Microsurgical Laboratories, Inc.,
dba Wexler Surgical Supplies
% Device for the Future
Ms. Lisa S. Jones
540 College Street
Bellaire, Texas 77401

Re: K110121
Trade/Device Name: Wexler Endoscope Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 02, 2011
Received: May 03, 2011

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K110121

Device Name: Wexler Endoscope Accessories

Indications for Use: The Wexler Endoscope Accessories are indicated for use in endoscopic surgical procedures to provide minimally invasive handling during the instrument's intended function. Clamps and forceps are used to grasp tissue or other items in the surgical field, while scissors are used to cut tissue or other items and needle holders are employed during the suturing process.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110121